Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Nose and Mouth Disinfection with Chlorhexidine on indicators of respiratory infections in intubated patients with mechanical ventilation

Protocol summary

Summary

The purpose of this study is to determinate the effect of disinfection of "mouth and nose" compared with antiseptic "mouth alone" with chlorhexidine solution on indicators of respiratory infection in intubated patients under mechanical ventilation. Research design: A randomized, double-blind clinical trial. Inclusion Criteria: The patient has oral endotracheal tube and connected to ventilator; The patient does not have nasogastric tube; On arrival to the ICU respiratory infection symptoms was not seen. Exclusion criteria: The patient is less than 48 hours under mechanical ventilation; Symptoms of respiratory infection is observed in the first two days of mechanical ventilation. Sample size:70 intubated patients under mechanical ventilation. Interventions: In the intervention group, antiseptic mouth and nose wash was done every 8 hours with 10 ml of 0.2% chlorhexidine preparation solution by the applicator for 30 seconds. in the control group, only oral antiseptic was used. Intervention time: For all patients, first intervention is performed in the first 12 hours connected to ventilator and this work continues until the end of the fifth day of mechanical ventilation. Primary outcomes: study of respiratory infection indicators based on clinical pulmonary infection score, including: amount of body temperature, amount and kind of Tracheal secretions, amount of Blood leukocytes, ratio of arterial Oxygenation, changes of chest radiographic and culture of tracheal secretions. Secondary outcomes: amount of Ventilator associated Pneumonia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051927969N1**
Registration date: **2016-07-09, 1395/04/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-09, 1395/04/19

Registrant information

Name
Mahdi Alimi
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Mashhad University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Nose and Mouth Disinfection with Chlorhexidine on indicators of respiratory infections in

intubated patients with mechanical ventilation

Public title
The Effect of Nose Disinfection with Chlorhexidine on Respiratory Infection
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: The satisfaction of patient's attendant to participate in the study; The patient's age is more than 18 years; The patient has endotracheal tube through the mouth; The patient has not nasogastric tube; Expecting mechanical ventilation for at least 48 hours; On arrival to the ICU lung infiltration on chest radiograph Does not exist; At least two of the three clinical criteria indicators of ventilator associated pneumonia (rectal temperature less than 35 or more than 38 degrees Celsius, leukocyte count of less than 4,000 or more than 12,000 per cubic millimeter of blood and purulent tracheal secretions) does not exist. Exclusion criteria: desire to continue participation in the study; Allergic reaction to chlorhexidine; Clear aspiration; At least two of the three clinical criteria indicators of ventilator associated pneumonia exist in the first or second day of mechanical ventilation
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Mashhad University of Medical Sciences
Street address
Qoreishi Building, Daneshgah St, Mashhad
City
Mashhad
Postal code
9177899191
Approval date
2015-11-07, 1394/08/16
Ethics committee reference number
IR.MUMS.REC.1394.493

Health conditions studied

1

Description of health condition studied
Pneumonia
ICD-10 code
J18.9
ICD-10 code description
Pneumonia, unspecified

Primary outcomes

1

Description
Amount of Body Temperature
Timepoint
up to Five Days after beginning of Intervention
Method of measurement
By Glass Thermometer for Axillary in Degrees Celsius

2

Description
Amount of Tracheal secretions
Timepoint
up to Five Days after beginning of Intervention
Method of measurement
Based on The Required Frequency of Tracheal Suctioning

3

Description
Kind of Tracheal secretions
Timepoint
up to Five Days after beginning of Intervention
Method of measurement
On the basis of color, odor and secretions concentration and according to the nurse caring for the patient

4

Description
Amount of Blood leukocytes
Timepoint
up to Five Days after beginning of Intervention
Method of measurement
By blood test

5

Description
Ratio of Arterial Oxygenation

Timepoint
up to Five Days after beginning of Intervention
Method of measurement
By Analyze of Arterial Blood Gases

6

Description
changes of Chest radiographic
Timepoint
up to Five Days after beginning of Intervention
Method of measurement
By the removable radiological devices (portable)

7

Description
Culture of tracheal secretions
Timepoint
up to Five Days after beginning of Intervention
Method of measurement
Quantitative culture with Gram stain

Secondary outcomes

1

Description
Ventilator associated Pneumonia
Timepoint
Up to five days after beginning of intervention
Method of measurement
By Clinical Pulmonary Infection Score

2

Description
The relationship between clinical criteria and diagnosis of pneumonia
Timepoint
Up to five days after beginning of intervention
Method of measurement
By Clinical Pulmonary Infection Score

Intervention groups

1

Description
In the intervention group, mouthwash (disinfection cheeks, gums, palate, tongue and teeth) every 8 hours with 10 ml of ready solution of 0.2% chlorhexidine is performed by the applicator for 30 second. Also every 8 hours after oral antiseptic, anti-infectious of nasal anterior openings is performed with 0.2% chlorhexidine solution by cotton swab. This continues until the end of the fifth day of mechanical ventilation.
Category
Prevention

2

Description
In the control group, mouthwash (disinfection cheeks, gums, palate, tongue and teeth) every 8 hours with 10 ml of ready solution of 0.2% chlorhexidine is performed by the applicator for 30 second. This continues until the end of the fifth day of mechanical ventilation. In this group is not done disinfection of nose.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Kamyab Hospital
Full name of responsible person
Street address
Shahid Kamyab Hospital, Fadaieyan Eslam Avenue, Nakhrisi Square, Mashhad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Saeid Eslami
Street address
Ghoraishy Building, University St, Mashhad
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahdi Alimi

Position
Nursing Expert, Nurse

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty